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APPLICATION NO. 08/813,950	FILING DATE 03/03/97	FIRST NAMED INVENTOR ASSMUS	ATTORNEY DOCKET NO. 383-252-0-FW
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EXAMINER SELLERS, R
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ART UNIT 1712	PAPER NUMBER 28
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DATE MAILED: 01/25/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
08/813,950

Applicant(s)  
Assmus And Petereit

Examiner  
Robert Sellers

Group Art Unit  
1712



☒ Responsive to communication(s) filed on Jan 13, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1 and 17-24 is/are pending in the application.

Of the above, claim(s) 1 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 17-24 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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This application contains claim 1 drawn to an invention nonelected with traverse in Paper No. 12. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The 35 U.S.C. 102(b) rejection over DeHaan et al is withdrawn since the claimed hot-melt application of the thermoplastic coating and binding agent at a temperature of from 100-150°C is not recited.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeHaan et al, Mueller et al and European Patent No. 204,596.

Seth is withdrawn since the disclosed melt mixing temperature of about 50°C (col. 9, lines 29-31) is not within the ambit of the claimed parameters.

DeHaan et al (col. 7, Example 1) shows the extrusion of a blend of a pharmaceutical active substance (i.e. theophylline), Eudragit RSPM acrylic plastic and cetyl alcohol. Mueller et al sets forth the melt extrusion of Eudragit RS and a polyethylene glycol at a temperature of preferably from 60-150°C (col. 3, lines 16-20). It would have been obvious to conduct the extrusions of DeHaan et al and the European patent within the temperature range of Mueller et al in order to facilitate the extrusion.

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The arguments filed January 13, 1999 have been considered but are not persuasive.

The presence of as little as 5% by weight relative to the acrylic plastic of the hydroxyalkyl(methyl)cellulose in the binder of Mueller et al would not affect the basic and novel characteristics of the binder defined in the claims since the identical utility as a binder for a medicinal composition is acknowledged and the specification on page 15, lines 25-26 is open to the inclusion of "other additives common in medicine coatings."

The European patent on page 8 exemplifies the melt mixing of a pharmaceutical active substance and cetyl alcohol at 65°C prior to extrusion. The claimed temperature range of from 100-150°C refers to the extrusion step in the mixing procedure according to page 16, lines 5-10 of the specification. It is a matter of ordinary skill in the art to conduct the extrusion of the European patent within the range of from 60-150°C as established in Mueller et al.

There is no evidence of record which indicates that the blend of acrylic polymer and liquid excipient of the European patent would not exhibit the claimed non-homogeneity once the extrudate has solidified.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication should be directed to Robert Sellers at telephone number (703) 308-2399 (Fax no. (703) 305-3599).

rs

1/21/99



ROBERT E. SELLERS  
PRIMARY EXAMINER  
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